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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/976,468	10/12/2001	Jorge DiMartino	12636-219	9964

21971 7590 11/19/2003

WILSON SONSINI GOODRICH & ROSATI
650 PAGE MILL ROAD
PALO ALTO, CA 943041050

EXAMINER

LEWIS, PATRICK T

ART UNIT PAPER NUMBER

1623

DATE MAILED: 11/19/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/976,468

Applicant(s)

DIMARTINO ET AL.

Examiner

Patrick T. Lewis

Art Unit

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19,21,22,25-27 and 31-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19,21,22,25-27 and 31-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 11.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group II, claims 19-33, in Paper No. 8 dated March 14, 2003 is acknowledged.

Applicant's Response dated September 5, 2003

2. In the Response dated September 5, 2003 claims 20, 23-24, and 28-30 were canceled. Claims 19, 21-22, 25-27, and 31-32 were amended. Applicant presented arguments directed to objections, rejections under 35 U.S.C. 102(b), and rejections under 35 U.S.C. 103(a). An action on the merits of claims 19, 25-27, and 31-33 is contained herein below.
3. The rejection of claims 19-20 and 22 under 35 U.S.C. 102(b) as being anticipated by Waller U.S. Patent 5,800,539 (Waller) has been rendered moot in view of applicant's amendments dated September 5, 2003.
4. The rejection of claims 19-29 and 33 under 35 U.S.C. 103(a) as being unpatentable over Waller U.S. Patent 5,800,539 (Waller) in combination with Trotta et al. Cancer Research, **1981**, Vol. 41, pages 2189-2196 (Trotta) and Spaner U.S. Patent 6,258,357 (Spaner) has been rendered moot in view of applicant's amendments dated September 5, 2003.
5. The objection of claims 30-32 as being dependent upon a rejected base claim has been rendered moot in view of applicant's amendments dated September 5, 2003.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 19, 21-22, 25-27, and 31-33 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The instant specification invites the skilled artisan to unduly experiment. Undue experimentation is a conclusion reached by weighing the noted factual considerations set forth below as seen in *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). A conclusion of lack of enablement means that, based on the evidence regarding each of the factors below, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation.

The factors include, but are not limited to:

1. The breadth of the claims,
2. The nature of the invention,
3. The state of the prior art,
4. The level of one of ordinary skill,
5. The level of predictability in the art,
6. The amount of direction provided by the inventor,
7. The existence of working examples, and

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8. The quantity of experimentation needed to make and/or use the invention based on the content of the disclosure.

Breath of Claims

Claim 19 is drawn to a method for preventing or reducing the risk of developing graft-versus-host disease in a recipient of an organ or tissue transplant, comprising administering to the transplant recipient pentostatin in a pharmaceutically effective amount within a predetermined time window after the transplantation. Claims 21-22, 25-27, and 31-33 ultimately depend from claim 19. Claims 21-22, 25-27, and 31-32 limit the mode of administration of pentostatin. Claim 33 requires the administration an immunosuppressive agent.

Nature of Invention

The invention relates to methods for the prevention of graft-versus-host disease employing pentostatin.

State of the Prior Art

The examiner directs applicant to Waller U.S. Patent 5,800,539 (Waller); Trotta et al. Cancer Research, **1981**, Vol. 41, pages 2189-2196; and Spaner U.S. Patent 6,258,357 (Spaner) cited in the 103 rejection in the Office Action dated June 3, 2003 regarding the state of the art in GVHD treatment and prevention.

Level of Ordinary Skill in the Art

The level of ordinary skill in the art is seen to be a M.D. experienced transplant surgery.

Level of Predictability in the Art /Amount of Direction Provided by the Inventor

Please note that a single embodiment may provide broad enablement in cases involving predictable factors, but more is required in cases involving unpredictable factors, such as chemical or physiological activity, see *Ex. parte Hitzeman*, 9 USPQ2d 1821. In the instant case, no data or citations of relevant prior art presented in support of applicant's assertion that GVHD is prevented by the administration of pentostatin after surgery. There has not been advanced an adequate written description which embraces the art's mode for preventing HVGD. There are no examples in the prior art wherein HVGD is prevented by the administration of an active agent following surgery. The instant specification provides no guidance as to how the skilled artisan would address various factors of concurrent co-administration of an immunosuppressive agent and pentostatin. Such factors include but are not limited to:

1. determination of the effects of the combination of drugs as they relate to their collective primary action chemically,
2. determination of the chemical properties of the combination of drugs (e.g., regarding collective interaction with cell receptors, toxicity, absorption), and
3. determination of the physical or structure-activity relationship between the combination of the active ingredients including cellular sites of drug action and modification of the active ingredients.

Working Examples

There are no working examples demonstrating the prevention of HVGD by administering pentostatin after surgery.

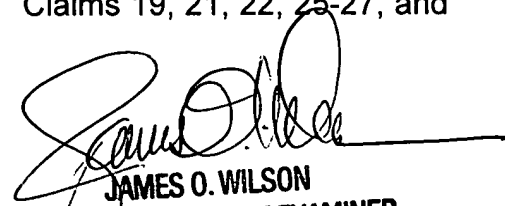
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Quantity of Experimentation Needed to make and/or use the Invention Based on the Content of the Disclosure

There is limited predictability in the art that pentostatin is able to prevent HVGD wherein pentostatin is administered after surgery. To provide adequate support for the breadth of the claims, applicant would have to provide sufficient evidence that a population of individuals was treated with pentostatin after surgery and that population did not develop HVGD. Applicant has failed to correlate via art-recognized evidence or adequate support in the instant disclosure the prevention of HVGD is prevented regardless of whether pentostatin is administered before or after surgery. As such, a skilled artisan would not recognize that pentostatin is capable of preventing HVGD by administering pentostatin after surgery.

Conclusion

8. Claims 19, 21, 22, 25-27, and 31-33 are pending. Claims 19, 21, 22, 25-27, and 31-33 are rejected. No claims are allowed.


JAMES O. WILSON
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

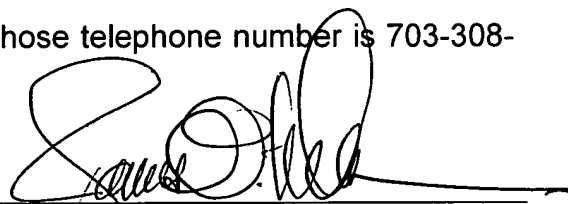
Contacts

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick T. Lewis whose telephone number is 703-305-4043. The examiner can normally be reached on M-F 10:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 703-308-4624. The fax phone number for the organization where this application or proceeding is assigned is 703-305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Patrick T. Lewis, PhD
Examiner
Art Unit 1623



James O. Wilson
Supervisory Patent Examiner
Technology Center 1600

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